DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

M3507n

WARNING LETTER

April 8, 1999

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dominic P. Rotella, Owner
Nichole Medical Equipment & Supply
2200 Michener Street
Suite 4
Philadelphia, PA 19115

Dear Mr. Rotella:

On March 9-10, 1999, Food and Drug Administration (FDA) Investigator Edward D. McDonald conducted an inspection of your facility located at 2200 Michener Street in Philadelphia, Pennsylvania, regarding the manufacture and distribution of oxygen, USP, for medical use. At the conclusion of the inspection, a Form FDA 483, List of Inspectional Observations (copy attached) was issued to and discussed with you. The FDA-483 dated March 10, 1999 lists serious deviations from Current Good Manufacturing Practice (CGMP) regulations for finished pharmaceuticals as outlined in Title 21 Code of Federal Regulations Part 211. Consequently, your product, compressed medical Oxygen USP, is adulterated under Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) in that the controls used for the manufacture, processing, packing, or holding of this product are not in conformance with CGMP regulations as follows:

1. Failure to perform identity and purity tests on each batch/lot of transfilled gaseous medical oxygen USP prior to release [21 CFR 211.165(a)].

FDA inspection determined that you possess a [redacted] Oxygen Analyzer, however, your Respiratory Therapist Technician admitted that he has never performed any finished product testing using the [redacted] analyzer. He also admitted that he has never calibrated the instrument.

2. Failure to have adequate batch production and control records for each batch of compressed medical oxygen USP produced, including documentation that each significant step in the manufacture of the batch was accomplished [21 CFR 211.188(b)].

3. Failure to identify each manifold fill of compressed medical oxygen USP with a traceable, unique lot number. [21 CFR 211.130(c) and 211.150(b)].

With respect to the manufacture of compressed medical gases the agency considers each manifold filling sequence a new lot requiring a unique lot number.

4. Failure to possess documentation that the following testing and inspection was performed on each batch of medical oxygen, USP: (a) Prefill tests/inspections: color check, hydrostatic date check, visual check; (b) Fill tests: leak test, final pressure and temperature; (c) Postfill test: leak test [21 CFR 211.84(d)(3)].

5. Failure to have detailed written procedures regarding all aspects of your compressed medical oxygen USP manufacturing operation [21 CFR 211.100(a)(b)].

Your firm must have in place written procedures regarding, prefill, fill and post fill operations; analytical testing; calibration and maintenance of equipment; distribution; and complaint handling. You should also implement written procedures for employee training and conducting recalls.

6. Failure to calibrate the transfilling manifold pressure and vacuum gauges used during the transfilling of medical oxygen USP [21 CFR 211.160 (b)(4)].

The above is not intended to be an all-inclusive list of violations which may exist at your firm. As top management, it is your responsibility to ensure that all requirements of the CGMP regulations are being met as well as all other requirements of the Act.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. This includes seizure and/or injunction.

Federal agencies are advised of the issuance of all Warning Letters regarding drugs and devices so that they may take this information into account when considering the award of contracts.

We are providing you with copies of the Compressed Medical Gas Guideline, Fresh Air "98", and 21 CFR Part 211 for your information and review.

Please advise this office in writing within fifteen (15) days of receipt of this letter as to the specific actions you have taken or intend to take to correct these violations. Your reply should be sent to the attention of Compliance Officer, James C. Illuminati at the above-referenced address.

Sincerely,

Thomas D. Gardine
District Director
Philadelphia District

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Enclosures:

(1) FDA-483 dated 3/10/99
(2) Compressed Medical Gases Guideline
(3) Fresh Air "98"
(4) 21 CFR Part 211

cc: PA Department of Health
Health and Welfare Building
7th and Forster Streets
P.O. Box 90
Harrisburg, PA 17120
Attn: Division of Primary Care and Home Health Services
Robert E. Bastian, Director